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EXAMINER	
LEE, YUN HAENG NMN	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,711	DRAKULIC, BUDIMIR	
	Examiner	Art Unit	
	YUN HAENG LEE	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41,44-54 and 78-109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41,44-54 and 78-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/08 has been entered.

Response to Arguments

2. Applicant's arguments filed 7/22/08 have been fully considered but they are not persuasive. Applicant argues that the fitting garment of Greene is not intended to be worn by the patient regardless of the patient size. Notwithstanding the intended use of the fitting garments of Greene, the largest available size will be capable of being worn by a patient having any individual one of the small, medium and large sizes, as Examiner explained in the last Office Action at the bottom of page 2. Applicant further argues that, with Green, there are no predetermined positions for receiving electrodes on the garment corresponding to predetermined positions in the patient, such as the V_1-V_6 positions, for each of different sizes of patients. This is incorrect as the numerous predetermined positions delineated by the grid-like arrangement 19 provide the predetermined positions for receiving electrodes on the garment. The predetermined positions in the patient will depend on the size of the patients, but, for each of different

sizes of patients, the corresponding predetermined positions in the patient will be located within the predetermined positions for receiving electrodes on the garment delineated by the grid-like arrangement 19. Regarding Applicant's argument regarding Greene's vest being custom made to fit only a single sized patient, instead of once again repeating a previously made statement, Examiner refers Applicant to the response to arguments in the last Office Action. Applicant further argues that Examiner has not cited any prior art reference which discloses amplifiers having characteristics of eliminating noise levels below that providing measurable interference with the signals on the electrode. This is also incorrect as Examiner cited a few exemplary references along with the Official Notice in the rejection of claim 1 in order to show that it is old and well known to use amplifiers when dealing with biological signals in order to reduce noise. For example, one of the examples cited by Examiner, Sipple (US Pat. No. 3,565,060), discloses using amplifiers to maintain a high signal-to-noise ratio. Finally, Applicant argues that Examiner seeks to rely on Official Notice in lieu of a supporting reference for the "direct connection" feature. Again, this is incorrect; nowhere does Examiner rely on Official Notice for showing the limitation of each amplifier being directly connected to a respective one of the electrodes. Rather, in the response to arguments in the last Office Action, Examiner stated that, "if one were to employ unity-gain amplifiers to ensure that doing a measurement of a voltage does not disturb the circuit producing the voltage to be measured, then it would be obvious to *directly connect* the unity-gain amplifiers to the measuring electrodes. Otherwise, the unity-gain amplifiers would not be able to accomplish the intended purpose of ensuring that the

measuring electrode does not disturb the circuit producing the voltage to be measured." (emphasis added)

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an amplifier for providing signals with a low level of noise, does not reasonably provide enablement for an amplifier for providing signals below a level providing measurable interference from noise. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Depending on the apparatus/method one employs, the level of interference from noise that could possibly be measured can vary and include an extremely low level of noise. It does not appear that the specification enables any person skill in the art to make an amplifier such that any degree of interference from noise would be immeasurable in any circumstance.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16, 18, 20-24, 29, 30, 44-54 and 95-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The terms "small", “medium” and “large” in claims 1-6, 19-31 and 78-109 are relative terms which render the claims indefinite. The terms "small”, “medium” and “large" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

8. The term "materially" in claims 16, 95-98 is a subjective term which renders the claim indefinite. The term "materially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Regarding claims 16, 18, 20-24, 26, 28-31, 44-54 and 95-98, it is unclear what degree of noise level would be considered affecting the characteristics of the signals and what degree would be considered not affecting the characteristics of the signals. Further in regard to claims 44-48, it is unclear what would constitute a change in the characteristics of the signals on the electrode and what would not; it appears that, in Applicant’s view, amplification by itself does not constitute a change in the characteristics.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4, 7-11, 16, 19-24, 29, 30, 32-41, 44-54 and 78-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330).

Regarding claim 1, Greene discloses in a combination for providing signals at predetermined positions in a patient,

a vest (10) constructed to be worn by the patient regardless of whether the patient has a small, medium or large size,

a plurality of electrodes (col. 1 lines 22-23) disposed at predetermined positions ($V_1 - V_6$) in the vest corresponding to said predetermined positions in the patient, and

the electrodes providing signals indicating characteristics of the heart of the patient having any individual one of the small, medium and large sizes, the predetermined positions of the electrodes for the patient of each individual one of the small, medium and large sizes being different from the predetermined positions of the electrodes for the patient having the other ones of the small, medium and large sizes (col. 1 lines 56-58).

Examiner took Official Notice in a previous Office Action that it is extremely old and well known to use amplifiers when dealing with biological signals in order to reduce noise, buffer signals, and provide a gain or amplitude increase. Lacking adequate traversal,

this feature has been taken to be admitted prior art. Some examples of this well-known feature can be found in Lasch et al. (US Pat. No. 3,554,188), Sipple (US Pat. No. 3,565,060) and Day (US Pat. No. 3,611,174) just to list a few. Thus, it would have been obvious to one of ordinary skill in the art to use amplifiers responsive to the signals on the electrodes at the predetermined positions in the vest of Greene for the patient having the individual one of the small, medium and large sizes for providing signals indicating characteristics of the patient's heart at the predetermined positions in the patient and with characteristics corresponding to the characteristics of the signals at the electrodes at the predetermined positions in the patient. Since the amplifiers would receive the signals from the electrodes, the signals that are provided by the amplifiers will necessarily have characteristics corresponding to the characteristics of the signals at the electrodes.

Regarding claim 2, Applicant admits in the present specification (page 10 lines 4-5) that the V_1-V_6 positions are well known in the prior art. Thus, it would have been obvious to one of ordinary skill in the art to position the electrodes of Greene at the positions V_1-V_6.

Regarding claim 3, Greene further discloses that the electrodes are disposed on the vest in rows and columns (col. 2 lines 36-43). Each of the electrodes in the vest will inherently be disposed in the vest in an individual one of the columns relative to the disposition of the other electrodes in the vest when the patient has an individual one of

the small, medium and large sizes if the electrodes are positioned to measure V_1-V_6 positions since, by definition, these positions do not overlap vertically.

Unity gain amplifiers such as those claimed in claim 3 are well known, as evidenced by Applicant's admission in the specification (col. 16 lines 19-20) that such amplifiers are commercially available. Certainly, Applicant is not the first to discover the utility of unity gain amplifiers. Thus, it would have been obvious to one of ordinary skill in the art to employ unity gain amplifiers in the vest of Greene.

Regarding claim 4, Greene further discloses that the positions in the vest are disposed in rows and columns (19). Each of the amplifiers, as discussed above, will inherently provide indications of the heart in an individual one of the rows at an individual one of the columns when the patient has the individual one of the small, medium and large sizes if the electrodes which provide the signals indicating the characteristics of the patient's heart at the different positions for the patient when the patient has a small, medium or large size are positioned to measure V_1-V_6 positions.

Regarding claims 7-11, and 19, the limitations are met by the above discussion.

Regarding claims 16, 20-24, 29, 30 and 49-54, Examiner took further Official Notice in a previous Office Action that it is old and well known to include a low-pass filter in an amplifier used for ECG signals to eliminate noise and other signal contaminants. One example of such an amplifier can be found in Taylor et al. (US Pat. No. 6,304,773).

Lacking adequate traversal, this feature is taken to be admitted prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include a low-pass filter in the amplifier discussed above to eliminate noise and other signal contaminants, substantially eliminating noise in the signals to a level below that affecting the characteristics of the signals, regardless of the size of the patient during ambulatory movements of the patient.

Regarding claims 32-39, the various claimed electrode configurations are simply in accordance with the V_1-V_6 positions which is old and well known as discussed above. Thus, the limitations are met by the above discussion.

Regarding claims 40, 41, 44 and 45, the limitations are met by the above discussion.

Regarding claim 46, Greene discloses various positions for the electrodes, including the front of the patient (such as in the V_1-V_6 positions) and the back of the patient (col. 1 lines 35-37). Examiner takes the position that electrodes disposed in either the front or the back of the patient are capable of providing for signals indicative of various problems. These various problems will differ in frequency of occurrence. Thus, some problems that are indicated by signals provided by electrodes disposed in the back of the patient will occur less frequently than some problems that are indicated by signals provided by electrodes disposed in the front of the patient.

Regarding claims 47, 48 and 78-109, the limitations are met by the above discussion.

12. Claims 5, 6, 12-15, 17, 18, 25-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (US Pat. No. 3,525,330) in view of the above discussion and further in view of Heilman et al. (US Pat. No. 5,078,134). Greene in view of the above discussion meets all the limitations of claims 5, 6, 12-15, 17, 18, 25-28 and 31 except for an inflatable member for inflating the vest/electrodes. Heilman et al. discloses an inflator (322) for inflating a vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface (col. 12 lines 20-21). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include an inflator in the vest/electrodes of Greene for inflating the vest/electrodes against the patient's body to reduce the impedance at the electrode/skin interface.

Conclusion

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUN HAENG LEE whose telephone number is (571)272-2847. The examiner can normally be reached on M-Th 10-8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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